

# The NCI SBIR Program

## NCI SBIR Funding Opportunities

### Reasons to Seek SBIR & STTR Funding

- Provides seed funding for innovative technology development projects
- Intellectual property rights are retained by the small business concern
- Not a loan – no repayment is required
- Doesn't impact stock or shares in any way (no dilution of capital)
- Provides recognition, verification and visibility
- Can be a leveraging tool to attract other funding (VC, etc.)

**A \$650M Program Annually at the NIH, \$105M at NCI**

### SBIR Eligibility Requirements

#### Small Business Concern

- Organized for-profit U.S. business
  - 500 or fewer employees, including affiliates
  - Must be:
  - At least 51% U.S.- owned by individuals and independently operated
- or
- At least 51% owned and controlled by another (one) business concern that is at least 51% owned and controlled by one or more individuals
  - Principal Investigator's primary employment must be with the Small Business Concern

### NIH Issues Multiple SBIR Solicitations

#### SBIR/STTR Omnibus Grant Solicitation

*Release:* January

*Receipt Dates:* April 5, August 5, and December 5

#### SBIR Contract Solicitation (NIH, CDC)

*Release:* August

*Receipt Date:* Early November

#### NIH Guide for Grants and Contracts

*Release:* Weekly

*Receipt Dates:* Various

For more information visit:

<http://sbir.cancer.gov/>

## **NCI SBIR ARRA Funding Opportunities**

- Up to \$10 million of ARRA funds committed to supplements for NCI Phase II SBIR/STTR grantees
- Administrative supplements for SBIR/STTR Workforce Enhancement to Accelerate the Commercialization of Novel Cancer-Related Innovations- deadline June 30, 2009
- [http://www.cancer.gov/pdf/recovery/admin\\_guidance\\_sbir.pdf](http://www.cancer.gov/pdf/recovery/admin_guidance_sbir.pdf)
- Competing revision supplements- deadline has passed

<http://sbir.cancer.gov/>

## **NCI is Moving to More Focused Solicitations**

- Goal is to improve success in commercialization by focusing on more directed research.
- Invest in the technology priorities of NCI that also have potential for commercialization
- Catalyze targeted technology development and draw private sector investment in areas such as drug development and cancer imaging
- Significantly increase the use of SBIR contracts.

## **NCI SBIR Technology Priorities – Last Cycle**

- Development of Molecular Pharmacodynamic Assays for Targeted Therapies
- System to Analyze and Support Biomarker R&D Strategies
- Development of Anticancer Agents
- Innovative Methods for Manufacturing Safe, Effective Cancer Therapeutics
- Innovative Strategies to Protect Radiosensitive Organs and structures During Radiation Therapy
- Quantitative Tissue Imaging For Clinical Diagnosis and Treatment
- Antibody Array for Cancer Detection and Diagnosis
- Novel and Improved Assays for Detecting Epigenetic Modifications
- Nanotechnology Imaging and Sensing Platforms for Improved Diagnosis of Cancer
- Mobile Computing for Consumer-centered Cancer Prevention and Control

## **New SBIR Bridge Award**

## **Phase II SBIR and Commercialization Success**

**Today, many awardees complete the SBIR Phase II award without advancing the technology far enough to attract private investment**

- Significant resources are required for getting through the FDA approval process
- This funding gap is known as the “Valley of Death”

## **SBIR Phase II Bridge Award**

### **Follow-on to SBIR Phase II**

- **Goal to help early-stage companies cross the “Valley of Death” by:**
  - Facilitating partnerships with third-party investors & strategic partners
  - Incentivizing third-party investments earlier in the development process by
  - **Sharing in the investment risk with third-party investors**

### **RFA Incentive Structure**

- **Gives competitive preference and funding priority to applicants that can raise substantial third-party funds (i.e., minimum 1:1 match)**
  - Affords NIH the opportunity to leverage millions in external resources
  - Third-party investors can provide valuable input in several ways:
    1. Rigorous commercialization due diligence prior to award
    2. Commercialization guidance during the award
    3. Additional financing beyond the Bridge Award project period

## **Phase II Bridge Pilot at NCI- 3 new RFAs in 2009**

**Third-party funds are expected to equal or exceed NCI funds being requested**

### **Third-party funds may include:**

- Cash, liquid assets, convertible debt

### **Sources of third-party funds may include:**

- Another company, venture capital firm, individual “angel” investor, foundation, university, state or local government, or any combination

### **Third-party investors are expected to bring:**

- Rigorous commercialization due diligence
- Commercialization guidance during the award
- Additional financing beyond the initial third-party investment

## **Original RFA Concept**

### **Technical Scope: Cancer Therapies & Imaging Technologies**

- Need for large amounts of capital for clinical validation and FDA approvals
- Opportunity to make a significant impact on many projects in the SBIR portfolio

### **Mechanism & Budgets**

- Uses the SBIR Phase II (R44) competing renewal mechanism
- Provides up to \$1 M per year for up to 3 years
- Available to current Phase II grant awards, and those that ended within last 2 years

### **Preferred Third-Party Matching Funds**

- Cash, liquid assets, convertible debt

### **Sources of Funds**

- Another company, venture capital firm, individual “angel” investor, foundation, university, state or local government, or any combination

## **Launched May 14, 2008**

### **Two Receipt Dates:**

- September 19, 2008
- February 27, 2009

### **Special Review Criteria**

- Balanced consideration of technical and commercial merits
- Detailed requirements for IP, regulatory and financing plans
- Complete disclosure of applicant’s SBIR commercialization history
- **Applications with strong financing plans are rewarded with higher score**

## Part I Overview Information

### Department of Health and Human Services

#### Participating Organizations

National Institutes of Health (NIH), (<http://www.nih.gov>)

#### Components of Participating Organizations

National Cancer Institute (NCI), (<http://www.cancer.gov>)

**Title:** SBIR Phase II Bridge Awards to Accelerate the Development of New Cancer Therapies and Cancer Imaging Technologies Toward Commercialization (SBIR [R44])

#### Announcement Type

New

**Request For Applications (RFA) Number:** RFA-CA-08-021

**NOTICE:** Applications submitted in response to this Funding Opportunity Announcement (FOA) for Federal assistance must be submitted electronically through Grants.gov (<http://www.grants.gov>) using the SF424 Research and Related (R&R) forms and the SF424 (R&R) Application Guide.

#### APPLICATIONS MAY NOT BE SUBMITTED IN PAPER FORMAT.

This FOA must be read in conjunction with the application guidelines included with this announcement in [Grants.gov/Apply for Grants](http://www.grants.gov/apply) (hereafter called Grants.gov/Apply).

A registration process is necessary before submission and applicants are highly encouraged to start the process at least four (4) weeks prior to the grant submission date. See [Section IV](#).

#### Apply for Grant Electronically

For Assistance downloading this or any Grants.gov application package, please contact Grants.gov Customer Support at <http://grants.gov/CustomerSupport>

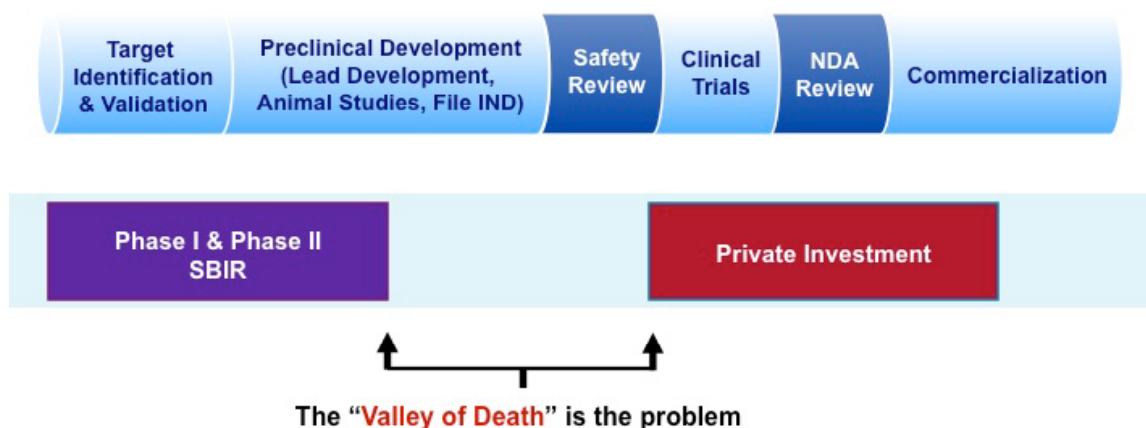
#### Catalog of Federal Domestic Assistance Number(s)

93.394, 93.395

#### Key Dates

Release/Posted Date: May 14, 2008

## Example: How the Bridge Award Would Apply in the Area of Drug Development



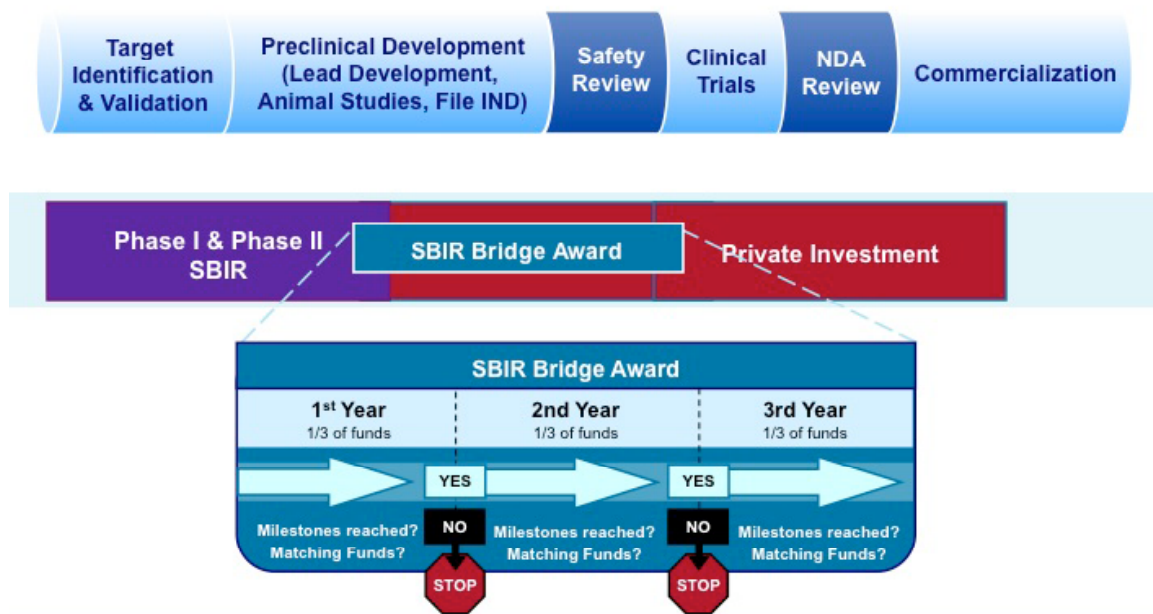
## Example: How the Bridge Award Would Apply in the Area of Drug Development



SBIR Bridge Award addresses the problem by bridging the “Valley of Death”

SBIR Bridge Award allows NIH to share investment risk by incentivizing investors or strategic partners to evaluate projects and commit funds much earlier

## Example: How the Bridge Award Would Apply in the Area of Drug Development



## **Expanded Technical Scope (FY10 reissuance)**

### **Therapeutics**

- Anticancer drugs and drug delivery systems
- Small molecules, biologics and vaccines

### **Devices for Cancer Therapy**

- Devices for therapeutic (anticancer) use of ionizing radiation
- Other ablative techniques

### **Imaging Technologies**

- Medical devices for in vivo cancer imaging
- Image-guided interventions (e.g., biopsy, surgery, drug delivery)
- Imaging agents

### **Cancer Diagnostics**

- *In vitro* diagnostics
- Any other diagnostic modality

## More Information on NCI SBIR & STTR Website

 National Cancer Institute

U.S. National Institutes of Health | [www.cancer.gov](http://www.cancer.gov)

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**Leading small business innovation and commercialization in the fight against cancer**

### What is the NCI SBIR & STTR Program?

The goal of the NCI is to eliminate the suffering and death due to cancer. The Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) Program is NCI's engine of innovation for developing and commercializing novel technologies and products to prevent, diagnose, and treat cancer.

The SBIR & STTR program is one of the largest sources of early-stage technology financing in the United States. We welcome entrepreneurs and small business leaders to this website to explore grant and contract funding opportunities and a new spirit of collaboration with the NCI.

[\[Learn More\]](#)

### Sign up for Updates

Sign up to receive updates and news about the NCI SBIR & STTR Program and upcoming opportunities.

### Latest Announcements

#### NCI SBIR & STTR Funding Opportunities

The following SBIR Grant Topics have been issued:

- [PAS-07-240](#)
- [PAS-07-241](#)
- [PAS-07-242](#)

**Receipt Dates:**  
April 5, August 5, December 5, 2007

[Read about more NCI SBIR & STTR funding opportunities.](#)

[Click here](#) to view videos from the NCI SBIR & STTR Program about how to apply for funding opportunities.

### Tips for Applying

<http://sbir.cancer.gov/>

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**Register on web site for funding opportunity updates**